Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 28, 2006

Wayne M. Samiere, President
Honolulu Fish & Seafood Corporation
Dba Honolulu Fish Company
824 Gulick Avenue
Honolulu, Hawaii 96819

Dear Mr. Samiere:

We inspected your seafood processing facility, located at 824 Gulick Avenue, Honolulu, Hawaii, on August 22, 23, 24, 25, and 28, 2006. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123, and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR 123 & 110). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated, raw, vacuum-packaged fish, including scombroid toxin forming species and non-scombroid toxin forming species; and fresh, scombroid toxin forming species, are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov.

Your significant violations were as follows:

- You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur and you must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a), and (b). However your firm does not have HACCP plan(s) for your refrigerated vacuum-packaged scombroid toxin forming species, such as mahi-mahi, and your refrigerated

vaccum-packaged non-scombroid fish such as mako shark, to control the food safety hazard of *Clostridium botulinum* toxin formation.

If you intend to market your refrigerated vacuum-packaged (not oxygen permeable) scombroid and non-scombroid fish without time temperature integrators on each individual package, you will need to evaluate the effectiveness of other preventative measures, either singularly or in combination with refrigeration. For information on the hazard of *Clostridium botulinum* formation in vacuum-packaged fish, we recommend that you read Chapter 13 in the Fish & Fisheries Products Hazards & Controls Guidance: Third Edition.

- You must have a HACCP plan that, at a minimum, lists monitoring procedures and their frequency for each critical control point, to comply with 21 CFR 123.6 (c) (4). However, your firm's HACCP plan for Tuna and Other Scombroid Species lists a monitoring frequency at the Chill Storage critical control point that is not adequate to control scombroid toxin (histamine) formation. Intermittent checks of the chiller air temperatures are not adequate for extended refrigerated hold times because they do not ensure that proper refrigerated temperatures were maintained between temperature checks. We recommend that in order to ensure maintenance of proper refrigeration temperatures, processors adopt methods that provide a continuous recording of refrigerated temperatures during refrigerated storage, e.g., recorder thermometer with a visual check of the instrument at least once per day. If you choose to check for the presence of ice, rather than refrigeration temperature, your monitoring procedure should include random checks of representative number of containers to ensure the presence of an adequate amount of ice at least twice per day. During our recent inspection, we noted that none of your scombroid toxin species were packed in ice.

- Because you chose to include a corrective action plan in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for "TUNA AND OTHER SCOMBROID SPECIES" at the Chill Storage critical control point to control histamine formation is not appropriate. Although sensory evaluation is acceptable, it is not adequate to ensure the safety of the affected product. FDA recommends that you perform histamine testing on the lot and reject the lot if the histamine level is greater than or equal to 50 ppm.

- You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for Tuna and Other

Scombroid Species lists a critical limit, "internal fish temperatures 40 degrees F or below; received from boats using [redacted] sensory evidence of proper shipboard handling, and no sensory evidence of extensive decomposition," at the Receiving critical control point that is not adequate to control scombroid toxin (histamine) formation. In addition to your critical limits for internal fish temperature and sensory examination, FDA recommends that you also ensure that all lots of scombroid toxin species are either accompanied with harvest vessel records or analyze a representative sample (a minimum of [redacted] fish) for histamine at receipt. A detailed list of appropriate critical limit options for use in conjunction with the either control strategy of monitoring harvest vessel records or analyzing for histamines can be found beginning on Page 88 of the Fish & Fishery Products Hazards & Controls Guidance, Third Edition.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation such as HACCP and verification records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation (21 CFR Part 123) and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Ms. Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Joseph P. Karr Jr.

Barbara J. Cassens
District Director
San Francisco District

cc: Damon S. Johnson, Vice President